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To whom it may concern

Thank you for the opportunity to provide comment on the November 2009 *Draft Guidelines for the Prevention of Intravascular Catheter-Related Infections*. I write entirely in my capacity as an independent global infection prevention consultant. The views expressed in this response are my own and do not represent any professional, government or commercial organization with which I am involved in either a voluntary or consulting capacity.

As you would appreciate, whilst CDC Guidelines are primarily written for constituents in North America, over time as they have become more readily available to international audiences they, along with much of CDC's public health work, have become globally recognised as "gold standard" guidance. In many countries, irrespective of their infection control capacity, or their level of regulatory control over available medical devices, CDC Guidelines hold a role as quasi national Guidelines. There are many global benefits to this situation. However, there is also a big risk for confusion among clinicians and perhaps even the delivery of poor quality patient care in the event of anomalies between CDC's recommendations and those in foreign lands. That confusion of course, is not limited to foreign lands as there are plenty of North American infection preventionists who sometimes struggle with interpretation and implementation of CDC Guidelines.

In an effort to prevent such confusion in the final version of the *Guidelines for The Prevention of Intravascular Catheter-Related Infections*, there are two important issues I would bring to HICPAC's attention. The first being use of needless systems and the second, the chlorhexidine concentration recommended for skin preparation.

Needless Systems
The set of evidence-based recommendations beginning at Line 1064 through to Line 1079 are sensible, easily implemented and potentially lifesaving. I commend HICPAC for the clarity this Guideline will bring to this issue which has to date been globally contentious. The recommendation as written is clear, concise and consistent with science.

I would also wish to bring HICPAC's attention to a manuscript scheduled for publication on 16 December 2009 and one on which I am a co-author.[1] The article is a multinational report of increased catheter-related bloodstream infections reported from a variety of institutions and settings in the USA and Australia. The findings and recommendations of that article highlight the value of using split septum technology in preference to mechanical valves, as recommended in this draft Guideline. Our work is yet another example of possible risk associated with the use of non-split septum valved technologies. This risk has been well described by several well respected authors and there is now a sufficiently reputable suite of high quality global evidence to support CDC's current recommendation.[2345]

Given the findings of our study and those of several other well respected experts I would request that HICPAC not amend any of the language as stated in lines 1077-1079, p.48. These lines are reproduced as follows.

5. Use a needleless system to access IV tubing. Category 1C
6. When needleless systems are used, the split septum valve is preferred over the mechanical valve due to increased risk of infection [336-339]. Category II
7.

The second issue which I would request HICPAC's attention is that relating to the concentration of Chlorhexidine required for pre-insertion skin disinfection. Again, this is an issue of contention. However most recent reputable Guidance, including the SHEA 2008 Compendium recommendations, which state *"apply an alcoholic chlorhexidine"solution containing a concentration of chlorhexidine gluconate greater than 0.5% to the insertion site."*[6] have recommended a Chlorhexidine concentration of >2%.

The ideal concentration for skin preparation is difficult to determine from the scientific evidence given the variability in formulations marketed around the world. My understanding is that different national regulatory agencies have imposed various stipulations resulting in a range of formulations (often marketed under the same brand name) with various chlorhexidine concentrations being available. The scientific studies are often limited to what's available in teh author's own country rather than necessarily being a true reflection of the issue. For many years in Australia we have used without harm, solutions of skin preparation that contain <2%

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[1] Jarvis W, Murphy C, Hall KK, et al. Health care-associated bloodstream infections associated with negative- or positive-pressure or displacement mechanical valve needleless connectors. Clin Infect Dis 2009;49: (epub ahead of print)

2 Rupp ME, Sholtz LA, Jourdan DR, et al. Outbreak of bloodstream infection temporally associated with the use of an intravascular needleless valve. Clin Infect Dis 2007; 44: 1408-14.

[3] Salgado CD, Chinnes L, Paczesny TH and Cantey JR. Increased rate of catheter-related bloodstream infection associated with use of a needleless mechanical valve device at a long-term acute care hospital. Infect Control Hosp Epidemiol 2007;28: 684-8.

[4].. Maragakis LL, Bradley KL, Song X, et al. Increased catheter-related bloodstream infection rates after the introduction of a new mechanical valve intravenous access port. Infect Control Hosp Epidemiol 2006;27: 67-70

[5] Field K, McFarlane C, Cheng AC, et al. Incidence of catheter-related bloodstream infection among patients with a needleless, mechanical valve-based intravenous connector in an Australian hematology-oncology unit. Infect Control Hosp Epidemiol 2007;28: 610-3.

[6] Marschall, J., L. A. Mermel, et al. (2008). "Strategies to prevent central line-associated bloodstream infections in acute care hospitals." Infect Control Hosp Epidemiol 29 Suppl 1: S22-30.

Chlorhexidine concentrations for IV site skin preparation. I understand that this issue has recently been a matter for consideration by Australia's HICPAC equivalent body who are currently tasked with revision of our national Infection Control Guidelines on behalf of our national Government. I further understand that after a systematic review of the literature, the Australian draft includes a recommendation for a minimum concentration of 0.5% chlorhexidine and 70% isopropyl Alcohol. The Australian recommendation is consistent with SHEA's 2008 recommendation and also with many of the comments submitted to CDC in the early weeks of this current comment period. On request I would happily connect any CDC staff with relevant Australian government authorities to discuss this matter.

The inconsistency between CDC's draft recommendation and that of SHEA and the Australian draft is a good example of how CDC, as the perceived authoritative global body, can potentially cause confusion among clinicians and hinder standardised practice. Both of these have potential to cause serious patient harm. Given the need to avoid this harm I would request specifically that HICPAC retain lines 1077-1079 (split-septum technology) exactly as written and that they revise all recommendations for pre-insertion skin disinfection to include a minimum of 0.5% Chlorhexidine concentration.

Thank you for your consideration of these comments and for the very important work HICPAC undertakes on behalf of the global infection prevention community.

Yours sincerely

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3rd December 2009